510(k) Summary

Biatain Ag Foam Dressings

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The assigned 510(k) number is: K100218

FEB 17 2010

510(k) Owner's Name: Coloplast A/S

Contact Person: Rebeka A. Stoltman
Manager, Regulatory Affairs
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411

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Date Prepared: January 22, 2010

Device Name and Classification

Trade Name:	Biatain Ag Foam Dressings
Common Name:	Topical Wound Dressing
Classification:	Unclassified; 21 CFR § 878.4020
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO

Manufacturer

Coloplast A/S
Holtedam 1
3050 Humlebaek, Denmark

Establishment Registration: 9610694
Owner/Operator: 8010144

Device Description

Biatain Ag Foam Dressings are wound dressings for exuding wounds with delayed healing due to bacteria, or where there is a risk of infection. Biatain Ag Foam Dressings consist of soft, absorbing polyurethane (PU) foam pads with a moisture-permeable PU topfilm on one side and a smooth, wound-contact surface on the other side. The foam is directly on the topfilm, except for Biatain Ag Cavity which has no topfilm. The foams contain silver, which is released upon contact with wound exudate.

The dressings are available in different sizes and shapes, including squares and rectangles, with rounded corners. Biatain Ag Non-Adhesive Foam Dressings also have bevelled edges. Foam thicknesses are 3 mm or 4.4 mm.

The dressings are individually-packed in a pouch. All dressings are sterile and are for single use only.

Substantial Equivalence Claim

The modified Coloplast Biatain Ag Foam Dressings are substantially equivalent in performance, indications, design and materials to Coloplast's currently marketed Contreet Adhesive and Non-Adhesive Foam Dressings and Contreet Cavity Foam Dressings, which were cleared under 510(k)s K022416 & K033869, respectively.

Indications for Use

Biatain Ag Foam Adhesive & Non-Adhesive Dressings are indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, post operative wounds and skin abrasions. Biatain Ag Foam Non-Adhesive Dressings are additionally indicated for diabetic foot ulcers.

Biatain Ag Foam Cavity Dressings are indicated for deep wounds with moderate to high amounts of exudate. Biatain Ag Foam Cavity Dressings are indicated for stage II, III and IV pressure ulcers, leg ulcers, diabetic foot ulcers and first or second degree burns with significant loss of tissue.

Summary & Conclusions of the Nonclinical Tests Submitted

Substantial equivalency is supported by bench testing compared to the predicate device and biocompatibility testing performed on the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Coloplast Corporation
Ms. Rebeka A. Stoltman
1601 West River Road North
Minneapolis, Minnesota 55411

FEB 17 2010

Re: K100218
Trade/Device Name: Biatain Ag Foam Adhesive & Non-Adhesive, & Cavity
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 22, 2010
Received: January 26, 2010

Dear Ms. Stoltman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ----------

Device Name: Biatain Ag Foam Adhesive & Non-Adhesive, & Cavity

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ulcers, diabetic foot ulcers and first or second degree burns with significant loss of tissue.

Daniel Kraus for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100218

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)